DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18,2014

OsteoMed
c/o Mrs. Piedad Pena, M.S.
Manager, Regulatory Affairs
3885 Arapaho Road
Addison, Texas 75001

Re: K140978
Trade/Device Name: OsteoMed Low Profile Orbital Plate System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: November 17, 2014
Received: November 18, 2014

Dear Mrs. Piedad Pena:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K140978

Device Name: **OsteoMed Low Profile Orbital Floor Plate System**

Indications for Use:

The OsteoMed Low Profile Plate System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit.

The OsteoMed Low Profile Plate System is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in adult patients.

Prescription Use: _X____ (Part 21 CFR 801 Subpart D)

And/Or

Over-The-Counter_____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

OsteoMed Low Profile Orbital Floor Plate System

Summary Date: November 17, 2014

Submitter Data:
OsteoMed
3885 Arapaho Road
Addison, TX 75001
972 677 4600
972 677 4601 (fax)

Primary Contact: Mrs. Piedad Pena, M.S.

Device Trade Name: OsteoMed Low Profile Orbital Plate System

Common Name: Orbital Floor Plate System

Classification Name: Plate, bone

Product Code: JEY- Bone Plate

Device Classification: 21 CFR Part §872.4760 – Bone plate

Legally Marketed Predicate Devices:
Synthes MatrixMIDFACE System (K031761)
Stryker Universal Orbital Floor Plate System (K123786)

Device Description:

The OSTEOMED Low Profile Orbital Floor Plate System is a permanent implant that is provided non sterile and is manufactured from commercially pure Titanium (ASTM F 67). The OSTEOMED Low Profile Orbital Floor Plates are offered with hole sizes which are able to accept 1.2mm and 1.6mm standard and auto drive bone screws and 1.5mm and 1.9mm safety screws and are offered in thicknesses ranging from .2mm to .5mm.

The implant is also provided in a variety of shapes including both non-preformed shapes and pre formed left and right profiles. The implant is fixed to the infra orbital rim via either the holes on the provided fixation arms or through the anterior screw holes on the plate itself to reconstruct the orbital floor and/or medial wall in adult patients.

The OsteoMed CFX system which is already available in the marketplace includes the screws (ASTM F136) and instrumentation to facilitate implantation of the Low Profile Orbital Floor Plate System. The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade

plastic. All instruments included in the CFX system are Class I, standard, manual, surgical instruments.

Intended Use/ Indications for Use:

The OsteoMed Low Profile Plate System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit.

The OsteoMed Low Profile Plate System is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in adult patients.

Performance Testing:

Mechanical testing was performed demonstrating the new OsteoMed Low Profile Plate System meets that of the predicate device, the Synthes MatrixMIDFACE System.

Performance equivalence was shown through the verification comparison to the predicate Synthes MatrixMIDFACE System (K031761).

Technological Characteristics:

The OsteoMed Orbital Floor Plate System is considered to be substantially equivalent in design, intended use and material to the predicate devices. There are not any design differences between the systems that would affect safety or effectiveness or raise new questions regarding safety and effectiveness.

Sterilization:

The OsteoMed Low Profile Orbital Floor Plate System components are single use, supplied non sterile and require sterilization prior to use.

Substantial Equivalence:

The basis of substantial equivalence for this device is based on similarities in intended use, indications for use, material, function, technology, performance, and operational principles to the predicate device; Synthes MatrixMIDFACE System which was cleared under K031761 on September 3, 2003 and the Stryker Universal Orbital Floor Plate System which was cleared under K123786 on April 9, 2013.

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Customer Service: (800) 456-7779

Device Comparison Chart:

Features	OsteoMed Low Profile Orbital Floor Plate System (NEW)	Synthes MatrixMIDFACE System (K031761)	Stryker Universal Orbital Floor System (K123786)
Intended Use / Indications for Use	**Intended Use:** The OsteoMed Low Profile Orbital Floor Plate System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit. **Indications for Use:** The OsteoMed Low Profile Orbital Floor Plate System is indicated for the reconstructive treatment of the orbital floor and/or medial wall trauma or bone excision in adult patients.	**Intended Use/Indications for Use:** The Synthes Craniofacial Plate and Screw System is intended for use in selective trauma of the midface and craniofacial skeleton, craniofacial surgery, reconstructive surgery of the maxilla and chin. **Indications:** Synthes MatrixMIDFACE Preformed Orbital Plates are intended for trauma repair and reconstruction of the craniofacial skeleton. -Orbital floor fractures -Medial orbital wall fractures -Combined orbital floor and medial wall fractures.	**Intended Use:** The Stryker Universal Orbital Floor System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit. **Indications for Use:** The Stryker Universal Orbital Floor System is indicated for the reconstructive treatment of the orbital floor and/or medial wall trauma or bone excision in adult patients.
Material & Biocompatibility	Plates are manufactured from CP (Pure) Titanium (as per ASTM F67).	Plates are manufactured from CP (Pure) Titanium.	Plates are manufactured from CP (Pure) Titanium, Grade 2.
Method of Fixation	Plate fixation with screws inserted through dedicated screw holes.	Plate fixation with screws inserted through dedicated screw holes.	Plate fixation with screws inserted through dedicated screw holes.
Sterility	Provided as single use, non sterile	Non sterile/sterile	Provided non sterile
Profile (Thickness) Range	.2mm- .5mm	.2mm-.5mm	.3mm- .6mm
Screw Diameters Accepted	1.2mm and 1.6mm screws 1.5mm and 1.9mm safety screws	1.5mm screws 1.85 mm safety screws	1.2mm and 1.4mm screws 1.7mm safety screws
Application Area	CMF/Orbital	CMF/Orbital	CMF/Orbital
Target Population	Adults	Unknown	Adults
Technology	Plates & Screw Fixation	Plates & Screw Fixation	Plates & Screw Fixation
Operational Principle	Reconstruct the orbital floor and/or medial wall.	Reconstruct the orbital floor and/or medial wall.	Reconstruct the orbital floor and/or medial wall.

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